



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,466	09/12/2000	Dinesh Mody	FMT1P029	6579

758 7590 08/23/2005

FENWICK & WEST LLP
SILICON VALLEY CENTER
801 CALIFORNIA STREET
MOUNTAIN VIEW, CA 94041

EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Pat

Office Action Summary	Application No.	Applicant(s)	
	09/660,466	MODY ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-39, 57, 78, 82-84, 89, 90, 100, 101 and 105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-39 is/are allowed.
- 6) ☒ Claim(s) 36, 57, 78, 82-84, 89, 90, 100, 101 and 105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 78, 82-84, 89, 90 and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Gough et al. (USPN 5,863,290).

Regarding claims 78, 86, 89 and 90, Gough et al. disclose a microwave ablation system (see third the paragraph beginning after the “summary of the invention” and the later discussion of the connection to the microwave energy source 20) as seen in figures 3-8 comprising an ablation device (16) that includes an energy delivery portion and an introducer (14) having a sharpened distal end and that is sized and dimensioned for slidable receipt of the ablation device there through. As seen for example in figure 3 (and explained in column 6, lines 30-60), the energy delivery device is made of a nitinol material and is selectively deployed to attain multiple shapes and sizes ranging from only “a few degrees from the longitudinal axis” to an obtuse angle embodiment described as a “j-hook” type. Additionally, Gough et al. disclose a device that is fully capable of performing the intended use as claimed, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since no structural limitation is recited the prior art meets the claimed invention. Additionally, it should be noted that Gough et al. also disclose that the elongated shaft has a sharpened distal end, a preshaped elongated energy delivery portion slidably disposed within the elongated shaft and a device capable of performing the recited intended use.

Regarding claims 82-84, Gough et al. further disclose an antenna (16) device that is preshaped and extends at an angle within the range of 0° and 90° or 45° and 135° with

Art Unit: 3739

respect to the longitudinal axis of the shaft, see col. 4-6 and figures 1-4. Furthermore, Gough et al. further disclose a dielectric layer (18) encapsulating the antenna (16), see col. 5, lines 23-45 and figures 1-8. Additionally, it should be noted the device of Gough et al. has pre-shaped energy delivery portion (16 in all or some of its embodiments) that extend substantially straight from the distal end at a skewed angle.

Regarding claim 105, Gough et al. disclose the claimed invention, see col. 1-14 and figures 1-10. Additionally, it should be noted that electromagnetic field (and radiation) is inherently concentrated on a side of the energy delivery portion at a particular point and/or set of points.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 51, 57, 100 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Gough et al. (USPN 5,863,290) in view of Kasevich (USPN 6,233,490 B1).

Regarding claims 36, 57 and 100, Gough et al. disclose a microwave treatment assembly comprising an elongate microwave antenna device (16), an introducer or elongate probe (14) that carries a portion of the antenna device within a lumen having a sharpened distal end (14') and allowing for the slidable displacement of the antenna device beyond the distal end of the probe, see col. 4-10 and figures 1, 3, 4, 6C, 9 and 10. Gough et al. also disclose a microwave power source, see col. 5, lines 46-57. Gough et al. disclose a substantially straight antenna (see figures 1-8). Gough et al. fail to explicitly recite an antenna device comprising a coaxial cable having an inner conductor, an outer conductor and a dielectric medium separating the inner and outer conductors and the antenna device electrically connected to the distal end of the inner conductor. It is well known that microwave antennas can be connected to the distal end of a coaxial cable having an inner conductor, an outer conductor and a dielectric medium in order to serve as a waveguide and radiate energy in the microwave frequency range in order to ablate tissue. For example it is well known that waveguides for TEM mode radiation must be in a coaxial form. Kasevich discloses a microwave antenna ablation system comprising a shaft (18) and microwave antennas (22, 24 and 26) coupled to the distal end of a coaxial cables (28, 30 and 32) in order to provide hyperthermal therapy, see col. 4-14 and figures 1-4. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gough et al., as is well known in the art and shown by Kasevich, to provide an alternate means of microwave energy propagation and radiation in the form of a microwave antennas connected to the distal end of a coaxial cable having an inner conductor, an outer conductor and a dielectric medium in order to

serve as a waveguide and radiate energy in the microwave frequency range in order to ablate tissue. Additionally, it should be noted the device of Gough et al. has pre-shaped energy delivery portion (16 in all or some of its embodiments) that extend substantially straight from the distal end at a skewed angle.

Regarding claim 101, Gough et al. further disclose an antenna (16) device that is preshaped and extends at an angle within the range of 0° and 90° or 45° and 135° with respect to the longitudinal axis of the shaft, see col. 4-6 and figures 1-4. Furthermore, Gough et al. further disclose a dielectric layer (18) encapsulating the antenna (16), see col. 5, lines 23-45 and figures 1-8.

Response to Arguments

Applicant's arguments filed 6/27/2005 have been fully considered but they are not persuasive. The examiner will address each argument/remark into.

Starting on the first page (page 1) of the "Remarks" section of the response filed 6/27/2005, Applicant summarizes the various amendments to the claims. On page 2 of the response, Applicant asserts that the further limitations contained in the amendments to the claims are not disclosed by the Gough et al. reference. The examiner could not disagree more strongly. As set forth by the claim language, the claimed invention is fully anticipated by Gough et al. (individually or in combination with other prior art of record). In fact the amendments to the

Art Unit: 3739

claims mostly present functional language that does not distinguish the claimed invention over Gough et al. (and the other prior art). Additionally, the examiner has previously pointed out how the Gough et al. reference meets all of the claimed structural features of the claimed invention and its intended uses (see previous office actions). Gough et al. discloses a number of embodiments that meet the claimed invention as broadly interpreted by the examiner. Applicant is relying on functional language and/or intended use to distinguish over the prior art, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Next, Applicant moves on to the rejections of claims 36, 57, 100 and 101. Applicant summarizes/recites the amendments to the relevant claims and asserts on page 4, that “These aspects of the claimed invention are not shown or suggested by the references considered either alone or in the combination proposed by the Examiner.” Here the examiner simply disagrees and suggests that Applicant is interpreting the claimed invention and prior art more narrowly than the examiner. Although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982). As broadly interpreted, the prior art (individually and/or collectively) meets the claimed structural features/limitations and is capable of performing the recited intended use.

Additionally Applicant asserts “this reference is understood to disclose ablating tissue within a tissue volume rather than from a surface or wall of the tissue volume using an antennae

Art Unit: 3739

that is shaped to the contour of such surface, in a manner as claimed by Applicants. Such shaping of the deployed antenna as claimed is not merely an expression of intended use but is a specific definition of the shape of the deployed antenna for ablating tissue in a tissue surface or wall that is penetrated by a shaft from which the antenna is deployed.” Applicant should note that as set forth by the claim language, the prior art discloses a device having the structural features necessary to meet the specific deployed antenna shape recited. Finally, although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982).

Applicant then refutes the combination of Gough et al. and Kasevich. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As a whole, the combination of Gough et al. and Kasevich meet the claimed invention. In addition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Finally, Applicant has amended the claims “variously”, as noted accordingly by Applicant, in an attempt to obviate the prior art. Additionally, Applicant has “a suggested correction of those analyses that are essentially focused on mere intended use, to recognize the specifically-claimed shape of the deployed antenna in the contour of the wall or surface of tissue to be ablated, for the described operative purposes.” In response, the examiner would like to note that Applicant has amended the claims with language that 1) provides or defines functionality and/or intended use that the prior art is capable of performing and/or 2) provides structural limitations, wherein these structural limitations as claimed are broad enough to be met by the prior art disclosures. In both and/or either cases, the amended claimed invention is met by the prior art of record. It is the examiner’s opinion that Applicant would be far better served by making amendments that clearly and concisely distinguish the claimed invention over the prior art, wherein these amendments should be point to clear, obvious and significant distinctions between the claimed invention and the prior art.

This action is FINAL.

Allowable Subject Matter

Claims 37-39 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
August 17, 2005


ROY D. GIBSON
PRIMARY EXAMINER